

Claims

What is claimed is:

1. A method of making an implantable bearing for an orthopaedic prosthesis, comprising the steps of:

5 exposing a first layer of polymer to a first dose of radiation;
securing said first layer of polymer to a second layer of polymer so as to create a composite; and
forming said composite into a predetermined shape of said implantable bearing.

10 2. The method of claim 1, further comprising the step of exposing said second layer of polymer to a second dose of radiation which is different than said first dose of radiation.

15 3. The method of claim 2, wherein said second dose of radiation is less than said first dose of radiation.

4. The method of claim 3, wherein said forming step comprises forming an articulating surface in said first layer of polymer.

20 5. The method of claim 2, wherein:
said step of exposing said first layer of polymer comprises exposing said first layer of polymer to said first dose of radiation so as to crosslink said first layer of polymer to a first degree, and

25 said step of exposing said second layer of polymer comprises exposing said second layer of polymer to said second dose of radiation so as to crosslink said second layer of polymer to a second degree which is less than said first degree.

30 6. The method of claim 1, wherein said securing step and said forming step are performed contemporaneously.

7. The method of claim 1, wherein said securing step comprises compression molding said first layer of polymer and said second layer of polymer to one another.

5 8. The method of claim 1, wherein:

both said first layer of polymer and said second layer of polymer comprise polyethylene, and

said securing step comprises fusing said polyethylene of said first layer of polymer to said polyethylene of said second layer of polymer.

10 9. The method of claim 1, wherein said forming step comprises forming said composite into an acetabular bearing which is adapted to be implanted into an acetabulum of a patient.

15 10. The method of claim 1, wherein said forming step comprises forming said composite into a glenoid bearing which is adapted to be implanted into a glenoid of a patient.

20 11. The method of claim 1, wherein said forming step comprises forming said composite into a tibial bearing which is adapted to be implanted into a tibia of a patient.

25 12. The method of claim 1, wherein:

said exposing step comprises exposing a first polymer preform to said first dose of radiation, and

said securing step comprises securing said first polymer preform to a second polymer preform so as to create said composite.

30 13. The method of claim 12, further comprising the step of exposing said second polymer preform to a second dose of radiation, which is less than said first dose of radiation, prior to said securing step.

14. The method of claim 1, wherein:

said exposing step comprises exposing a polymer powder to said first dose of radiation, and

5 said securing step comprises securing said polymer powder to a polymer preform so as to create said composite.

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14. The method of claim 14, further comprising the step of exposing said polymer preform to a second dose of radiation, which is different than said first dose of radiation, prior to said securing step.

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16. The method of claim 1, wherein:

said exposing step comprises exposing a polymer powder to said first dose of radiation, and

porous structure so as to create said composite.

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17. The method of claim 16, further comprising the step of exposing said polymer porous structure to a second dose of radiation, which is different than said first dose of radiation, prior to said securing step.

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18. The method of claim 1, wherein:

said exposing step comprises exposing a polymer porous structure to said first dose of radiation, and

polymer preform so as to create said composite.

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19. A method of making an implantable bearing for an orthopaedic prosthesis, comprising the steps of:

securing a layer of crosslinked polymer to a layer of non-crosslinked polymer so as to create a composite; and

forming said composite into a predetermined shape of said implantable bearing.

20. The method of claim 19, wherein said securing step and said forming step are performed contemporaneously.

21. The method of claim 19, wherein said securing step comprises compression molding said layer of crosslinked polymer and said layer of non-crosslinked polymer to one another.

22. The method of claim 19, wherein:

both said layer of crosslinked polymer and said layer of non-crosslinked polymer comprise polyethylene, and

said securing step comprises fusing said polyethylene of said layer of crosslinked polymer to said polyethylene of said layer of non-crosslinked polymer.

23. The method of claim 19, wherein said forming step comprises forming said composite into an acetabular bearing which is adapted to be implanted into an acetabulum of a patient.

24. The method of claim 19, wherein said forming step comprises forming said composite into a glenoid bearing which is adapted to be implanted into a glenoid of a patient.

25. The method of claim 19, wherein said forming step comprises forming said composite into a tibial bearing which is adapted to be implanted into a tibia of a patient.

26. The method of claim 19, wherein said securing step comprises securing a crosslinked polymer preform to a non-crosslinked polymer preform.

27. The method of claim 19, wherein said securing step comprises securing a crosslinked polymer preform to a non-crosslinked polymer powder.

28. The method of claim 19, wherein said securing step comprises securing a crosslinked, polymer porous structure to a non-crosslinked polymer powder.

29. The method of claim 19, wherein said securing step comprises securing a crosslinked polymer porous structure to a non-crosslinked polymer preform.

30. The method of claim 19, wherein said forming step comprises forming an articulating surface in said layer of crosslinked polymer.

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31. An orthopaedic prosthesis, comprising:

an implantable bearing which is prepared by a process comprising the steps of (i) exposing a first layer of polymer to a first dose of radiation, (ii) securing said first layer of polymer to a second layer of polymer so as to create a composite, and (iii) forming said composite into a predetermined shape.

32. The orthopaedic prosthesis of claim 31, wherein said process for preparing said implantable bearing further comprises the step of exposing said second layer of polymer to a second dose of radiation which is different than said first dose of radiation.

33. The orthopaedic prosthesis of claim 32, wherein said second dose of radiation is less than said first dose of radiation.

34. The orthopaedic prosthesis of claim 33, wherein said process for preparing said implantable bearing further comprises the step of forming an articulating surface in said first layer of polymer.

35. The orthopaedic prosthesis of claim 32, wherein:

said step of exposing said first layer of polymer comprises exposing said first layer of polymer to said first dose of radiation so as to crosslink said first layer of polymer to a first degree, and

5 said step of exposing said second layer of polymer comprises exposing said second layer of polymer to said second dose of radiation so as to crosslink said second layer of polymer to a second degree which is less than said first degree.

10¹⁴ 36. The orthopaedic prosthesis of claim 31, wherein said securing step and said forming step are performed contemporaneously.

15¹⁵ 37. The orthopaedic prosthesis of claim 31, wherein said securing step comprises compression molding said first layer of polymer and said second layer of polymer to one another.

20 38. The orthopaedic prosthesis of claim 31, wherein:
both said first layer of polymer and said second layer of polymer comprise polyethylene, and

 said securing step comprises fusing said polyethylene of said first layer of polymer to said polyethylene of said second layer of polymer.

25 39. The orthopaedic prosthesis of claim 31, wherein said implantable bearing is an acetabular bearing which is adapted to be implanted into an acetabulum of a patient.

40. The orthopaedic prosthesis of claim 31, wherein said implantable bearing is a glenoid bearing which is adapted to be implanted into a glenoid of a patient.

30 41. The orthopaedic prosthesis of claim 31, wherein said implantable bearing is a tibial bearing which is adapted to be implanted into a tibia of a patient.

42. The orthopaedic prosthesis of claim 31, wherein:
said exposing step comprises exposing a first polymer preform to said first
dose of radiation, and
5 said securing step comprises securing said first polymer preform to a
second polymer preform so as to create said composite.

10 43. The orthopaedic prosthesis of claim 31, wherein said process for
preparing said implantable bearing further comprises the step of exposing said second
polymer preform to a second dose of radiation, which is less than said first dose of
radiation, prior to said securing step.

15 44. The orthopaedic prosthesis of claim 31, wherein:
said exposing step comprises exposing a polymer powder to said first dose
of radiation, and
20 said securing step comprises securing said polymer powder to a polymer
preform so as to create said composite.

25 45. The orthopaedic prosthesis of claim 44, wherein said process for
preparing said implantable bearing further comprises the step of exposing said polymer
powder to a second dose of radiation, which is different than said first dose of radiation,
prior to said securing step.

30 46. The orthopaedic prosthesis of claim 31, wherein:
said exposing step comprises exposing a polymer powder to said first dose
of radiation, and
25 said securing step comprises securing said polymer powder to a polymer
porous structure so as to create said composite.

30 47. The orthopaedic prosthesis of claim 46, wherein: said process for
preparing said implantable bearing further comprises the step of exposing said polymer
porous structure to a second dose of radiation, which is different than said first dose of
radiation, prior to said securing step.

48. The orthopaedic prosthesis of claim 31, wherein:
said exposing step comprises exposing a polymer porous structure to said
first dose of radiation, and
5 said securing step comprises securing said polymer porous structure to a
polymer preform so as to create said composite.

10 49. An implantable bearing for an orthopaedic prosthesis, comprising:
G a crosslinked layer of polymer; and
U a non-crosslinked layer of polymer secured to said crosslinked layer of
S polymer.

5 50. The implantable bearing of claim 49, wherein said crosslinked layer
15 of polymer and said non-crosslinked layer of polymer are compression molded to one
C another.

15 51. The implantable bearing of claim 49, wherein both said crosslinked
C layer of polymer and said non-crosslinked layer of polymer comprise polyethylene.

20 52. The implantable bearing of claim 49, wherein:
G said crosslinked layer of polymer has an articulating surface defined
U therein, and
S said non-crosslinked layer of polymer has an engaging surface defined
C therein which is adapted to be secured to an acetabulum of a patient.

25 53. The implantable bearing of claim 49, wherein:
G said crosslinked layer of polymer has an articulating surface defined
U therein, and
S said non-crosslinked layer of polymer has an engaging surface defined
C therein which is adapted to be secured to a glenoid of a patient.

54. The implantable bearing of claim 49, wherein:

said crosslinked layer of polymer has an articulating surface defined therein, and

5 said non-crosslinked layer of polymer has an engaging surface defined therein which is adapted to be secured to a tibia of a patient.

55. The implantable bearing of claim 49, wherein said crosslinked layer of polymer has an articulating surface defined therein.

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56. An implantable bearing for an orthopaedic prosthesis, comprising:
0 a first layer of polymer which is crosslinked to a first degree; and
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0 a second layer of polymer secured to said first layer of polymer, said
0 second layer of polymer is crosslinked to a second degree that is different than said first
0 degree.
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57. The implantable bearing of claim 56, wherein said second degree is
0 less than said first degree.

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58. The implantable bearing of claim 57, wherein said first layer of
20 polymer has an articulating surface defined therein.

59. The implantable bearing of claim 56, wherein said first layer of
polymer and said second layer of polymer are compression molded to one another.

25 60. The implantable bearing of claim 56, wherein both said first layer of
polymer and said second layer of polymer comprise polyethylene.

30 61. The implantable bearing of claim 56, wherein:
said first layer of polymer has an articulating surface defined therein, and
said second layer of polymer has an engaging surface defined therein
which is adapted to be secured to an acetabulum of a patient.

62. The implantable bearing of claim 56, wherein:
said first layer of polymer has an articulating surface defined therein, and
said second layer of polymer has an engaging surface defined therein
which is adapted to be secured to a glenoid of a patient.

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63. The implantable bearing of claim 56, wherein:
said first layer of polymer has an articulating surface defined therein, and
said second layer of polymer has an engaging surface defined therein
which is adapted to be implanted into a tibia of a patient.

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64. The method of claim 1, wherein at least part of at least one of said
first layer of polymer and said second layer or polymer is melted during the securing
step.

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65. The method of claim 1, wherein the step of securing said first layer
of polymer to said second layer of polymer so as to create said composite comprises
melt-fusing said first layer of polymer and said second layer of polymer together.

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66. The method of claim 1, further comprising the step of sterilizing said
formed implantable bearing using a surface irradiation technique, and wherein the step
of sterilizing said formed implantable bearing is adequate for pre-implant sterilization.

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67. The method of claim 19, wherein at least part of one of said layer of
crosslinked polymer and said layer of non-crosslinked polymer is melted during the
securing step.

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68. The method of claim 19, wherein at least one of said layer of
crosslinked polymer and said layer of non-crosslinked polymer is melted during said step
of securing said layer of crosslinked polymer to said layer of non-crosslinked polymer
so as to create said composite.

69. The method of claim 19, wherein said step of securing said layer of crosslinked polymer to said layer of non-crosslinked polymer so as to create said composite comprises melt-fusing said layer of crosslinked polymer and said layer of non-crosslinked polymer together.

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70. The method of claim 19, further comprising the step of sterilizing said formed implantable bearing without gamma irradiation, and wherein the step of sterilizing said formed implantable bearing is adequate for pre-implant sterilization.

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71. The orthopaedic prosthesis of claim 31, wherein at least part of at least one of said first layer of polymer and said second layer of polymer is melted during said step of securing said first layer of polymer to said second layer of polymer so as to create said composite.

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72. The orthopaedic prosthesis of claim 31, wherein said step of securing said first layer of polymer to said second layer of polymer so as to create said composite comprises melt-fusing said first layer of polymer and said second layer of polymer together.

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73. The orthopaedic prosthesis of claim 31, wherein said implantable bearing is sterilized after said composite is formed into said predetermined shape without using gamma irradiation.

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74. The orthopaedic prosthesis of claim 31, wherein the polymer material of the first layer of polymer has a fully consolidated form with an ultimate tensile strength, the polymer material of the second layer of polymer has a fully consolidated form with an ultimate tensile strength, wherein the first layer of polymer is secured to the second layer of polymer at an interface, and wherein the interface has an ultimate tensile strength comparable to the ultimate tensile strength of at least one of the polymer materials of the first and second layers of polymer.

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5 75. The orthopaedic prosthesis of claim 31, wherein the polymer material of the first layer of polymer has a fully consolidated form with an elongation at break, the polymer material of the second layer of polymer has a fully consolidated form with an elongation at break, wherein the first layer of polymer is secured to the second layer of polymer at an interface, and wherein the interface has an elongation at break at least comparable to the elongation of break of at least one of the polymer materials of the first and second layers of polymer.

10 76. An implantable bearing for an orthopaedic prosthesis, comprising:
 a first layer of a first polymer material, said first polymer material being available in a fully consolidated form having mechanical and dynamic properties;
 a second layer of a second polymer material, said second polymer material being available in a fully consolidated form having mechanical and dynamic properties;
 the first and second layers of polymer materials being secured together at an interface into a composite, wherein the first and second layers of polymer material are secured together in a process involving heating at least one of the layers of polymer material;
 wherein the interface has mechanical and dynamic properties corresponding with the mechanical and dynamic properties of the fully consolidated form of the first polymer material and fully consolidated form of the second polymer material;
 and wherein at least one of the mechanical and dynamic properties of the interface is comparable to at least one of the corresponding mechanical and dynamic properties of the fully consolidated forms of the first polymer material and second polymer material.

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77. The implantable bearing of claim 76, wherein said mechanical and dynamic properties are selected from the group consisting of:

ultimate tensile strength;
yield strength;
elongation to break;
modulus;
impact strength;
creep resistance;
compression strength;
shear strength; and
fatigue strength.

78. The implantable bearing of claim 77, wherein the interface has an ultimate tensile strength at least as great as the ultimate tensile strength of the weaker of the fully consolidated forms of the first and second polymer materials.

79. The implantable bearing of claim 76, wherein the interface is free from any void, gap, pore, crack, or separation that would allow ingress of agents that could compromise sterilization.

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80. The implantable bearing of claim 76, wherein the first layer of first polymer material is selected from the group consisting of:

- (a) crosslinked UHMWPE; and
- (b) crosslinked ethylene homopolymer; and

5 said second layer of polymer material is selected from the group consisting of:

- (a) UHMWPE;
- (b) crosslinked UHMWPE;
- (c) ethylene homopolymer;
- (d) ethylene copolymer including an acrylate monomer selected from the group consisting of methyl acrylate, methyl methacrylate, ethyl acrylate, ethyl methacrylate, and butyl methacrylate;
- (e) polyetheretherketone;
- (f) polyetherketone;
- (g) polyetherketoneetherketoneketone; and
- (h) polyimide.

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82. The implantable bearing of claim 81, wherein said at least one characteristic is selected from the group consisting of:

- (a) the presence of crosslinking;
- (b) the degree of crosslinking;
- 5 (c) wear resistance;
- (d) creep resistance;
- (e) oxidation resistance;
- (f) ductility;
- (g) toughness;
- 10 (h) ultimate tensile strength;
- (i) yield strength;
- (j) elongation to break;
- (k) modulus;
- (l) presence of an acrylate monomer;
- (m) presence of a ketone group in the polymer chain;
- (n) presence of nitrogen in a polymer chain; and
- 15 (o) chemical family.

20 83. The implantable bearing of claim 76, wherein said interface lacks any void, pore, crack, or separation that would allow ingress of agents that could compromise sterilization.

25 84. The implantable bearing of claim 76, wherein the first and second layers are secured together by hot isostatic pressing.

85. The implantable bearing of claim 76, wherein the first and second layers are secured together by welding.

30 86. The implantable bearing of claim 76, wherein the first and second layers are secured together at the interface by melt-fusion.

87. The implantable bearing of claim 76, wherein said first and second layers are secured together at the interface during compression molding.

5 88. The implantable bearing of claim 76, wherein the first layer has an articulating surface defined thereon and the second layer has an engaging surface defined thereon.

10 89. The implantable bearing of claim 88, wherein the engaging surface is adapted to be secured to an acetabulum of a patient.

15 90. The implantable bearing of claim 88, wherein the engaging surface is adapted to be secured to a glenoid of a patient.

20 91. The implantable bearing of claim 88, wherein the engaging surface is adapted to be secured to a tibia of a patient.

25 92. The implantable bearing of claim 88, wherein the engaging surface is adapted to be secured to another component.

30 93. The implantable bearing of claim 76, wherein:
the first layer is selected from a group of starting materials consisting of a crosslinked powder, a crosslinked preform and a crosslinked porous structure; and
the second layer is selected from a group of starting materials consisting of an non-crosslinked powder and an non-crosslinked preform.

35 94. The implantable bearing of claim 76, wherein:
the first layer is selected from a group of starting materials consisting of crosslinked powder and crosslinked preform; and
the second layer is selected from a group of starting materials consisting of a non-crosslinked porous structure.

95. An implantable bearing for an orthopaedic prosthesis, comprising:
a first polymer layer having a surface;
a second polymer layer having a surface;
the first and second polymer layers being secured together at an interface
5 into a composite;
wherein the interface of the composite is free from any void, pore, gap,
crack, or separation that would allow ingress of agents that could compromise
sterilization.

10 96. The implantable bearing of claim 95, wherein the first polymer layer
is selected from the group consisting of:
(a) crosslinked UHMWPE; and
(b) crosslinked ethylene homopolymer; and
15 said second polymer layer is selected from the group consisting of:
(a) UHMWPE;
(b) crosslinked UHMWPE;
(c) ethylene homopolymer; and
(d) ethylene copolymer including an acrylate monomer selected from
20 the group consisting of methyl acrylate, methyl methacrylate, ethyl acrylate, ethyl
methacrylate, and butyl methacrylate.

97. The implantable bearing of claim 95, wherein said first polymer layer
has at least one characteristic different from said second polymer layer.

98. The implantable bearing of claim 97, wherein said at least one characteristic is selected from the group consisting of:

- (a) presence of crosslinking;
- (b) degree of crosslinking;
- 5 (c) wear resistance;
- (d) creep resistance;
- (e) oxidation resistance;
- (f) ductility;
- (g) toughness;
- 10_{uu} (h) ultimate tensile strength;
- (i) yield strength;
- (j) elongation to break;
- (k) modulus;
- 15_{uu} (l) presence of an acrylate monomer; and
- (m) chemical family.

20 99. The implantable bearing of claim 95, wherein the first and second polymer layers are secured together in a process that includes heating at least one of the first and second layers.

25 100. The implantable bearing of claim 99, wherein the first and second polymer layers are secured together at the interface by melt-fusion.

101. The implantable bearing of claim 99, wherein the first and second polymer layers are secured together at the interface by welding.

30 102. The implantable bearing of claim 95, wherein first and second polymer layers are secured together at the interface during compression molding.

103. The implantable bearing of claim 95, wherein the first layer has an articulating surface defined thereon and the second layer has an engaging surface defined thereon.

104. The implantable bearing of claim 103, wherein the engaging surface is adapted to be secured to an acetabulum of a patient.

5 105. The implantable bearing of claim 103, wherein the engaging surface is adapted to be secured to a glenoid of a patient.

106. The implantable bearing of claim 103, wherein the engaging surface is adapted to be secured to a tibia of a patient.

107. The implantable bearing of claim 103, wherein the engaging surface is adapted to be secured to another component.

108. A method of making an implantable bearing for an orthopaedic prosthesis, comprising the steps of:

15 109. securing two layers of polymer together to form a composite; and sterilizing the composite without exposing the composite to gamma irradiation.

20 110. The method of claim 108, wherein the step of securing two polymer layers together to form a composite comprises melt-fusion of the two polymer layers.

111. The method of claim 108, wherein the step of sterilizing the composite comprises surface sterilization of the composite.

25 112. The method of claim 110, wherein surface sterilization of the composite is selected from the group consisting of ethylene oxide sterilization and gas plasma sterilization.

112. The method of claim 108, wherein the first polymer layer is selected from the group consisting of:

- (a) crosslinked UHMWPE; and
- (b) crosslinked ethylene homopolymer; and

5 said second polymer layer is selected from the group consisting of:

- (a) UHMWPE;
- (b) crosslinked UHMWPE;
- (c) ethylene homopolymer;
- (d) ethylene copolymer including an acrylate monomer selected from

10 the group consisting of methyl acrylate, methyl methacrylate, ethyl acrylate, ethyl methacrylate, and butyl methacrylate.

113. The method of claim 108, wherein the first polymer layer has at least one characteristic different from the second polymer layer.

114. The method of claim 113, wherein said at least one characteristic is selected from the group consisting of:

- (a) presence of crosslinking;
- (b) degree of crosslinking;
- (c) wear resistance;
- (d) creep resistance;
- (e) oxidation or corrosion resistance;
- (f) ductility;
- (g) toughness;
- (h) ultimate tensile strength;
- (i) yield strength;
- (j) elongation at break;
- (k) modulus;
- (l) presence of an acrylate monomer; and
- (m) chemical family.

115. The method of claim 108, wherein the first and second polymer layers are secured together in a process that includes heating at least one of the first and second layers.

5 116. The method of claim 115, wherein the first and second polymer layers are secured together at the interface by melt-fusion.

117. The method of claim 115, wherein the first and second polymer layers are secured together at the interface by welding.

10 118. The method of claim 115, wherein said first and second polymer layers are secured together at the interface during compression molding.

119. The method of claim 108, wherein the first layer has an articulating surface defined thereon and the second layer has an engaging surface defined thereon.

120. The method of claim 119, wherein the engaging surface is adapted to be secured to an acetabulum of a patient.

20 121. The method of claim 119, wherein the engaging surface is adapted to be secured to a glenoid of a patient.

122. The method of claim 119, wherein the engaging surface is adapted to be secured to a tibia of a patient.

25 123. The implantable bearing of claim 119, wherein the engaging surface is adapted to be press fit to another component.